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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/730,559	12/07/2000	Tetsuyoshi Ishiwata	766.21 CIP	9523

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FITZPATRICK CELLA HARPER & SCINTO
30 ROCKEFELLER PLAZA
NEW YORK, NY 10112

EXAMINER

WOITACH, JOSEPH T

ART UNIT PAPER NUMBER

1632

DATE MAILED: 04/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/730,559

Applicant(s)

ISHIWATA ET AL.

Examiner

Joseph T. Woitach

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 4, 6, 8, 9, 14-17, 20, 21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5, 7, 10-13, 18 and 19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

This application, filed December 7, 2000, is a continuation in part of application 09/090,672, filed June 4, 1998, which is a continuation in part of PCT/JP97/04468, filed December 5, 1997.

Claims 1-21 are pending and currently under examination.

Election/Restriction

Applicant's election with traverse of Group 7, SEQ ID NO: 7, claims 1-2, 5, 7, 10-13, 18 and 19, made on January 20, 2004 is acknowledged. The traversal is on the ground(s) that a DNA sequence is not complex and request that nine additional sequences be rejoined with the elected invention. (See Applicants initial election filed April 1, 2003.) This is not found persuasive because as noted in the restriction requirement, each of the polynucleotide sequences are unique one to the other, and would not anticipate or make obvious each other. Each of the different sequences specifically listed in the claims would require a separate search and consideration. It is noted however, because each of the sequences are presented in the first claim, claim 1 represents a linking claim.

In this case, claim 1 link(s) inventions 1-37. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claim 1. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s)

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are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Because the restriction groups are the same and only the relationship has been addressed, the requirement is still deemed proper and is therefore made FINAL.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claims 1-21 are pending. Claims 4, 6, 8, 9, 14-17, 20 and 21 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement. Claims 1-3, 5, 7, 10-13, 18 and 19, as they are drawn to a DNA related to IgA nephropathy as set forth in SEQ ID NO: 7.

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Information Disclosure Statement

The information disclosure statements filed comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 . A signed copy of the IDS forms are provided with the instant action.

Priority

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Japan on December 5, 1996. It is noted, however, that applicant has not filed a certified copy of the Japanese application as required by 35 U.S.C. 119(b). Should applicant desire to obtain the benefit of foreign priority under 35 U.S.C. 119(a)-(d) prior to declaration of an interference, a translation of the foreign application should be submitted under 37 CFR 1.55 in reply to this action.

In addition, Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application); the disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994). Specifically, the present application is a CIP of 09/090,672 and a comparison of the disclosures indicates that the present disclosure is the first presentation of the specific sequence set forth as SEQ ID NO: 7 (compare for example '672 Table 2, page 59

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with Table 2, page 75 in the instant application). It is noted that clones designated as INM063-7 was presented, however this does not provide the specific support for SEQ ID NO: 7 currently under examination. Accordingly, the claims presently under examination are given the priority date as of the filing date of the instant application.

Claim Objections

Claims 10-13 are objected to because of the following informalities: these claims depend on claims that have been withdrawn as being drawn to non-elected inventions. The claims should be amended to be independent claims. For the sake of compact prosecution, the claims will be interpreted to encompass all the limitations of the claims on which they depend.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 5, 18 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the metes and bounds of claim 1 are indefinite because the specific hybridization conditions required by the claim are not clearly set forth. What one would consider 'stringent' is relevant and subject to change, therefore the metes and bounds are not sufficiently defined where one would know if any particular sequence would be encompassed by the claim. Dependent claims are included in the rejection because they fail to

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address the basis of the rejection and only recite potential uses for sequence encompassed by the claim.

Claims 5 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the claims are vague and unclear in what would be considered a diagnostic DNA. It appears that this is drawn to an intended use of a DNA and it is unclear what structurally properties are required to meet this limitation set forth in the claims.

Claims 7 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the claims are vague and unclear in what would be considered a therapeutic DNA. It appears that this is drawn to an intended use of a DNA and it is unclear what structurally properties are required to meet this limitation set forth in the claims.

Claims 10-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the claims are vague and unclear in what would be considered an activity related to IgA nephropathy. Claims 10-13 have been interpreted to encompass the limitations of claim 9 that require encoding a protein that has a particular activity, however this activity is not defined in the claim nor the present disclosure. It is unclear what functional and more specifically what structurally properties are required to meet this limitation set forth in the claims.

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5, 7, 10, 12, 18 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Rouault *et al.*

Claims 1-3, 5, 7, 10-13, 18 and 19 are under examination as they are drawn to a DNA related to IgA nephropathy as set forth in SEQ ID NO: 7. Claim 1 requires that the sequence hybridize, claim 2 requires that the sequence be 5 to 60 residues, and claim 3 indicates that it is selected from a specific group of SEQ ID NOs. Dependent claims indicate that the sequence is diagnostic (claims 5 and 18), therapeutic (claims 7 and 19). Claims 10-13 are being interpreted to encompass a DNA that encodes a protein encompassed by claim 9 and includes protein sequences that have been modified. The exact ‘activity related to IgA nephropathy’ is not specifically set forth, and is being interpreted to encompass similar limitations as set forth in claims 1-3 because of their intended uses set forth in claims 5, 7, 18 and 19.

Rouault *et al.* each a polynucleotide sequence that encodes the human IRP2 protein. Sequence homology searches confirm the teaching in the present disclosure that SEQ ID NO: 7 is related to IRP2.

Claims 1-3, 5, 7, 18 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Genbank entry M58511.

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Claims 1-3, 5, 7, 18 and 19 are summarized above. M58511 is a polynucleotide sequence that encodes the human IRP2 protein. Sequence homology searches confirm the teaching in the present disclosure that SEQ ID NO: 7 is related to IRP2.

Claims 1-3, 5, 7, 10-13, 18 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Samaniego *et al.*

Claims 1-3, 5, 7, 10, 11, 12, 18 and 19 are summarized above. Claim 13 is drawn to a method of making a protein by expressing the DNA in culture. Samaniego *et al.* teach a polynucleotide sequence that encodes the human IRP2 protein. Sequence homology searches confirm the teaching in the present disclosure that SEQ ID NO: 7 is related to IRP2. Finally, Samaniego *et al.* teach a method where the sequences are used to generate an IRP2 protein by expressing and purifying the protein from a cell culture.

Conclusion

No claim is allowed. In addition it is noted that the linking claim has not been found allowable, therefore, the search and consideration of other specific sequence was not performed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (571) 272-0734.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

Joseph T. Voitach

Joe Voitach
AU 1632